Response to OSC Supplemental Questions to the VA OMI

OSC DI-15-2103 SUPPLEMENT SEPTEMBER 16, 2016

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RE: OSC FILE DI-15-2103

September 16, 2016

Dear Attorney Bradley:

Thank you for the opportunity to respond to the Office of Special Counsels supplemental queries regarding my allegations at the Raymond G. Murphy Veterans Affairs Medical Center, (Albuquerque) OSC File DI-15-2103. As a former federal employee, retired Marine and stakeholder I felt it my duty and obligation to address these severe failings and health risks at the Raymond G. Murphy Veterans Affairs Medical Center.

In the Office of Medical Inspectors report, I am still left with deep concerns as I read their investigation results. To substantiate one out of the four allegations does not set well with me. I did not place myself in this position to be marginalized, however I am left with the feeling that I was. I have come to the conclusion that this is the nature of the VHA and VA. They do not appreciate the truth.

My decision to disclose my concerns to the Congressional Sub Committee on Investigations and Oversight - Veterans Affairs in January 2015 was after I believed that I had exhausted all means within the Raymond G. Murphy VAMC. In doing my duty and fulfilling my moral obligation to the oath I took, my co-workers, fellow veterans and their families is bittersweet.

In closing, I would like to again thank you for assisting me throughout this entire process.

Semper Fidelis,

Alfred Edward Smith III

USMCR Retired

Chinle, Arizona

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OSC Question 1*: The VA agency report did not substantiate the allegation that surgery technicians habitually fail to conduct point-of-use pre-treatment despite the fact that the report listed the following issues with the Albuquerque VA point-of-use practices. Considering the facts listed below, why did the VA find the allegation unsubstantiated?*

- *Two of six SPS day shift members interviewed reported that instruments were inadequately sprayed with Prepzyme. Does this mean that the four other SPS day shift members consistently found that instruments were sprayed with Prepzyme?*
- *Three of the five SPS staff members on the evening shift indicated that they did not consistently see evidence of point-of-use pretreatment on instruments received from the OR. Please clarify this statement. Does it mean that the three of five SPS staff members consistently saw evidence of a failure to use point-of-use treatment? If so, why was this insufficient to substantiate the allegation?*
- *None of the SPS staff members were able to articulate the Prepzyme manufacturer's IFU that instruments should be cleaned within 4 hours of application.*

VA Response: OMI interviewed surgical technicians who all indicated that they consistently used Prepzyme after every case. We also reviewed SOPs from the OR that outlined the procedure for applying Prepzyme after each case. OMI found inconsistent reporting of observations by the SPS staff on the use of Prepzyme. Reports of the day shift personnel were inconsistent: two reported no issues with equipment coming from the OR, one reported dry instruments; and one reported bloody and wet instruments. Another stated that he would re-apply Prepzyme if he saw that case carts had been sitting too long. The significant issue here was the amount of time the SPS staff left case carts unprocessed in the decontamination area of SPS: untreated instruments left too long would dry up; treated ones would appear bloody and wet at first, then the Prepzyme and dissolved bodily materials would drip off.

Three staff members on evening shift described dry instrument trays and pooling of liquid on the bottom of the case cart. This would be the appearance of the carts following the application of Prepzyme by the surgical technicians (as they reported), but so long a wait in the decontamination area that the compound had dripped off the instruments into the bottom of the cart. Had the Prepzyme not been used, the instruments would not have dripped onto the bottom of the carts. All the evening shift staff stated that they "always" confronted multiple unprocessed case carts at the start of their shift.

A. Smith III Response 1: From my observations at the RGM VAMC, Medical Supply Technicians (MST) initial training was primarily accomplished by On the Job Training (OJT). Level 1 and Level II training *was* conducted online as time permitted, however the department relied on technicians who had been there the longest to shadow and evaluate the newest technicians. This was to include seasoned technicians such as myself who possessed more training. Certified Medical Supply Technicians (CMST) primarily utilize the Central Service Technical Manual (CSTM), published by the International Association of Healthcare Central Service Material Management (IAHCSMM) as the international guideline for certification, re-certification and continuing education (CE). This was in lieu of the defunct SPD manual 7176.

The CSTM was the standard manual utilized by CMST technicians for guidance in reprocessing and aseptic protocols. This is pertinent to this report because the OMI utilized resources other than the CSTM in determining the technician's responses regarding comprehension of aseptic and reprocessing best practices by SPS technicians. In the OMI summation of the report there is no mention of the CSTM definition of point-of-use processing. (IAHCSMM, pg. 494).The differentiation the report makes in regards to decontamination and "pretreatment" is important. (pg.6). CSTM states that "*instrument decontamination begins at point-of-use, and is then continued in the Central Service (SPS) decontamination area."* (IAHCSMM pg. 125).

In the article, "*Preventing bio-film formation in flexible endoscopes,*" Putnam states, "*during the initial stages of bio-film formation, bacteria are only loosely attached to the surface and can easily be detached by cleaning."* The author further states, "*…as the bacteria proliferates and the bio-film matures, the attachment becomes much stronger, limiting the effectiveness of cleaning solutions and scrubbing.* (Putnam). This is especially true in the instance of critical RME such as endoscopes. *Contaminated flexible endoscopes have been linked to more health care-associated infections than any other medical device.* (Putnam). The delay in reprocessing of this critical RME has severe repercussions.

The reference by the OMI regarding the condition of the surgical case carts: *dried, dripping and pooling of blood* is evidence of hydrating with Prepzyme. In the case of critical and semi-critical RME that was routinely co-located within these surgical case carts, re-hydrating and allowing t critical RME to dry and pool creates incrustation: the hardening of bio-burden to and within the interior channels, often found in difficult to reach areas by flushing and brushing.

Dr. Michelle J. Alfa, an international research expert in the field of infectious disease. She is a Professor at the University of Manitoba, Principal Investigator, Infectious Diseases, St. Boniface Research Centre Winnipeg, Canada. Dr. Alfa has authored numerous research publications in the healthcare industry. Dr. Alfa's principle research is in the areas of:

- Clostridium difficile infections: spore reservoirs in the healthcare environment;
- Medical device associated infections: role of cleaning errors in infection transmission
- Role of the Gut Microbiome in health of the elderly
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In a conversation centered on the effects of RME to continuous hydrating and the delay of reprocessing, she concluded that…*"there is evidence (data) to demonstrate that due to the microbial buildup associated with not reprocessing the endoscopes in a timely manner accompanied with continuous hydrating of endoscopes, the transmission rate of bacterial microbial averages at approximately 45%, which is an extremely high rate."* (Smith/Alfa. September 12, 2016). The percentage rate of 45% translates to 1 in every 2 patients that are subjected to this transmission of the antibody organisms due to microbial buildup. The infection rate is lower than transmission rate but the patient acquires multi-antibiotic resistant organisms or Carbapenem-resistant Enterobacteriaceae (CRE), due to improperly reprocessed medical devices. (Smith/Alfa). CRE are a family of germs that are difficult to treat because they have high levels of resistance to antibiotics. CRE can cause infections when they enter the body, often through medical devices. CRE are an important emerging threat to public health. (Healthcare. January 23, 2015). In a difference of opinion with the OMI, the significant issue should be: was Prepzyme re-applied simply to the surface contents of the case cart or the inner channels/lumens of the RME contained? I submit that it was the former, rendering the RME highly susceptible to the risk of CRE. Not only does commingling of RME result in additional processing time as is documented by the OMI, it also results to a high risk to healthcare workers and patient health.

OSC Question 2: *The lack of documented delivery time of instruments from the OR to SPS is a serious concern as it can have a significant impact on the effectiveness of decontamination procedures. The Agency Report includes a recommendation to begin documenting the time from end of case to instrument delivery. What is the timetable for when such documentation would begin? How, where, and by whom would begin? How, where, and by whom would documentation be performed?*

VA Response #2: The Medical Center developed a post-procedure case-care audit based on the Censitrac system that time-stamps each step of the process from the OR to SPS decontamination. Since launching the audit in November 2015, the Medical Center has been completing 30 audits per month and providing immediate feedback to the OR staff. SPS began tracking the instruments in June 2015, after fully training its transport staff on the Censitrac system.

A. Smith III Response 2: SPS does not have a transport staff, unless this report is referring to the OR staff transporters? My concern here is what is being tracked? In the SPS, there was conflict on accurately tracking surgical case carts utilizing Censitrac. Do we scan the surgical case cart or the RME inside? Routinely, surgical case carts were returned to the SPS with RME from different procedures inside. This meant that, instead of scanning the surgical case cart, each scanned piece of RME had to be checked and scanned for accuracy, instead of scanning the surgical case cart.

After the case cart contents are scanned to the surgical case cart, all of the RME within the case cart should be returned to the SPS in the same surgical case cart. What I saw as routine was RME from different OR suites. This means that the SPS decontamination technician must spend extra time to scan each RME individually to ensure accurate tracking and accountability; it also would lessen the opportunity of missing, lost and unaccountable RME. This translates to being able to monitor the true life of RME.

OSC Question 3*: The agency report states that the Medical Center recognized their SOPs were not in compliance with the IFUs and were addressing the problem by re-writing all 200+ SPS SOPs. What is the status of this re-writing process and when can it be expected to be completed?*

VA Response: the facility held a competency training fair on the newly updated SOPs in March 2016 and has documented ongoing competency training in June 2016. The Medical Center finished re-writing all remaining SOPs in need of updating by July 2016. Competency training is ongoing. Some SOPs require annual training, and the most recently completed ones are on the schedule for the next training sessions.

A. Smith III Response 3: There were multiple inspections from The Joint Commission, and the National Program Office for Sterile Processing (NPOSP). These inspections continuously pointed out issues such as SOPs, documented training was non-compliant. When I pressed management for SOP revisions, as well as continuing education and goals for training, I felt ignored and my suggestions relegated to little or no importance. I do not comprehend why SPS management, specifically the Assistant Chief is not being held accountable for this failure. The coincidental release of the revised VHA Directive 1116 (2) Sterile Processing Service (March 2016) should have a positive impact on the SPS.

OSC Question 4*: The VA Agency Report did not substantiate the allegation that SPS decontamination and sterile preparation areas are not cleaned on a regular basis. Considering the facts listed, why did the VA find the allegation unsubstantiated?*

VA response: We did not substantiate the allegation based on several pieces of evidence. We reviewed daily cleaning logs from 2009-2015, signed by the Environmental Management Service (EMS) cleaning staff. These cleaning logs are required in the EMS SOP for SPS. Based upon the extensive documentation over several years. Based upon the extensive documentation over several years, fabrication of these documents is improbable. The EMS SOP for SPS outlines the responsibilities in detail: documentation of completed cleaning on the cleaning log; mandatory cleaning from Monday through Friday from 3:30 p.m. to midnight; daily cleaning responsibilities including decontamination and clean area; special cleaning that includes wall washing, dumb waiter cleaning, regulated and general waste removal; linen removal; moping responsibilities including dust, damp mopping and floor burnishing; vent cleaning; horizontal surface cleaning; vacuuming in office areas; cleaning of trash receptacles and waste carts. In compliance with its SOP, the posted cleaning schedule is in the office of the SPS supervisor and the checklist of the scheduled tasks is in the SPS sterile processing area. Based upon our inspection of the entire SPS area on multiple visits during the inspection, the unprompted and detailed recitation of the cleaning schedule and SOP processes by the EMS technician assigned to the area, and the documentation provided by the cleaning logs convinced the team of compliance with the SOP by EMS.

Additionally, the EMS supervisor provided an email between the former Chief of SPS, Assistant Chief of SPS and himself. In this email, the EMS supervisor indicated the Assistant Chief of SPS declined the invitation to inspect the area with him to locate any deficits in EMS support because the Assistant Chief of SPS said "everything was getting done." The EMS supervisor provided the same option to inspect the area with the former Chief of SPS and received no response. The date on this email was March 17, 2015.

The National Program Office for Sterile Processing (NPOSP), VISN, and OMI did not identify any deficiencies in the cleanliness of the SPS areas during their visits in March 2015, June 2015 and August 2015 respectively. There is an SPS SOP on cleaning sterilizers based upon the manufacturers operating instructions. There is evidence of annual training competencies on this SOP for SPS technicians. The Medical Center also provided a receipt for annual sterilizer chamber cleaning by an outside contractor dated September 2015.

A. Smith III Response 4: During my tenure, the sterilizers were a constant hazard. There was no weekly cleaning of the sterilizers per industry protocol. Due to this, as I outlined to the OMI I question the quality and sterility of the RME that was reprocessed in the steam and Sterrad and Gas sterilizers. Annual chamber abrasion cleaning does not render the equipment safe for use; the Sterrad sterilizer, a sterilizer that exploits the synergism between peroxide and low temperature gas plasma (an excited or ionized gas) to rapidly destroy microorganisms, was utilized for months, even though it constantly alerted staff that it consistently required maintenance. It took months for SPS

management to get a vendor in to service the sterilizers. SPS staff continued to utilize this sterilizer to meet client needs at their own risk. On one occasion, I was injured while a vendor was performing maintenance on the Sterrad sterilizer. It caused me to miss three (3) days of work and even though I was sent home by the RGM VAMC physician on duty, SPS management attempted to deprive me of pay for those days by running me AWOL.

OSC Question 5: *While agency inspections did not uncover EMS deficiencies, numerous SPS employees reported various concerns with EMS performance.*

- *Assistant Chief of SPS said the EMS support was a joke*
- *Multiple interviewees reported incidents of overflowing trash containers*
- *Multiple interviewees reported the presence of dust bunnies*
- *The EOC inspections for SPS that the VA report partially relied upon did not inspect the decontamination and sterile preparation areas, which were the areas at issue in the report.*
- *There was no indication that HEPA filters had been changed regularly, only that the issue of HEPA and other filter changes was addressed with SPS leadership and that the vendor provides the sterilizer filters under a maintenance agreement. We request more information regarding when and how often HEPA filters in SPS facilities are changed.*

VA Response: While the SPS leadership working the day shift were largely unaware of the EMS SOP, cleaning schedule, or checklist requirements, despite these items being in plain view in their office and clean processing areas, the evening shift leadership was acutely aware of them. EMS cleans during the evening shift per its schedule, and all the evening shift staff reported that EMS support from the primary EMS technician was "wonderful." The Assistant Chief of SPS worked the day shift and could not articulate the EMS SOP and was not aware of the schedule posted in SPS. She provided no evidence of concerns with EMS other than her opinion statement. The overflowing trash receptacles resulted from large amounts of disposable personal protective equipment (PPE) waste at the end of shifts. EMS regularly emptied these in accordance with their SOP and came to SPS at other times whenever called. The Medical Center corrected this by obtaining larger trash receptacles. We saw no dust bunnies in any area of SPS, nor were these reported by the previous two inspections noted in question 4 above. The ongoing cleaning by EMS at the scheduled times was prominently posted in SPS, documented by the signed checklist, and confirmed by evening shift staff. Medical Center leadership has added the decontamination areas to Environment of Care (EOC) rounds, and requires its staff to don appropriate PPE when conducting these periodic inspections.

In response to our request for evidence that the vendor regularly replaced HEPA filters, the Medical Center provided an ongoing maintenance agreement with vendor (Getinge) that covers routine preventive including annual replacement of HEPA filters. Their invoices showed filter replacements in September 2014, July 2015, and August 2016.

A. Smith III Response 5: The monitoring of house-keeping in the SPS was not a priority to the SPS management. I concur with the findings by the OMI in the report. This activity should be constantly monitored to ensure compliance. The lack of cleaning in all areas of the SPS creates unwanted microorganisms within the sterile area of the SPS; this affects the quality of the sterilization, especially in the sterile prep area of the SPS; while I do not question the response of the EMS unit in regards to the frequency of the house keeping in the SPS, I would ask that the VHA consider utilizing a validation system such as the Ultra-Violet Visible Marker (UVM) system that would enable EMS supervisors to validate cleaning of certain areas. Information regarding this type of device is located in the attachments: *The Journal of Hospital Infection.* (Alfa, M.J. 2013). This study was co-authored by Dr. Alfa.

OSC Question 6: *What is the VA's response to the whistleblowers contention that there are numerous deficiencies in the way the Albuquerque VA handles Dental RME?*

- *Dental cassettes are inadequate to contain the different types of procedural trays as they permit the sharp, pointed tips of the instruments to protrude through, potentially risking injury to staff and puncturing the packaging*
- *VA report notes during inspection of stored dental RME, the VA found over a dozen oil-stained packages containing sterilized dental hand pieces*

- *The whistleblower claims that current SOPs do not properly explain the proper way to clean dental hand pieces.*

VA Response: There was no evidence of the inadequacy of dental cassettes to contain instruments. No reports exist of staff having been injured when handling dental instruments.

We did notice oil-stained packages of dental hand pieces and removed them from service immediately. Dental clinic staff complained that a number of hand pieces had lacked oil. We determined that this was due to *the use of a vacuum cycle in the sterilizer that drew the oil (injected prior to sterilization) out of the hand piece.* As the manufacturer's instructions for use for the hand piece contained no information about gravity or vacuum settings for the sterilizer, we contacted the vendor and learned that a vacuum setting on the sterilizer was a problem, and the vendor recommended gravity settings only for this dental equipment. We informed the facility immediately, and SPS made appropriate changes for sterilizing this equipment.

A. Smith III Response 6: Dental RME was scheduled for pickup at least twice daily. This meant at least once during the 1st shift and once by the 2nd shift. There days when the 2nd shift was overwhelmed with the pickup and had to provide two (2) SPS for the pickup, because the 1st shift supervisor failed to supervise that this task was completed. Coupled with the abundance of surgery case carts awaiting the 2nd shift for reprocessing, vendor loaner trays, and clinic RME, the dental cassettes and hand-pieces, at times took a low priority, but they were processed during the 2nd shift. By the end of the shift, fatigued MSTs went through the motion of wiping, oiling and passing the dental hand-pieces through the pass thru window.

Dental procedure cassettes are made of metal and contain numerous instruments. Many are needle pointed and poke through the vented slots, presenting a hazard to the handler; when the cassettes have completed the washer/disinfector stage, they are extremely hot after they complete this stage and dripping wet; there is a cool off period, however, because they are slotted, water is trapped within and when transferring the cassettes to the work station for sterilization preparation, it was not uncommon to have a wet floor. This is not ideal in a sterile area. I repeatedly recommended the department purchase a sterile dryer unit for this purpose but, it was not acted upon.

Due to my previous training, on numerous occasions I pointed out to SPS management that the hand-pieces were not being reprocessed properly. I demonstrated that gross bio-matter (blood, tooth enamel, oil) was being sterilized rendering the hand-pieces un-sterile after they were passed through to the sterile side. This bio-matter was located in the head of the hand-pieces the most critical part that comes in direct contact with the inside of the patients mouth and teeth during procedures. I still question the sterility of the hand-pieces that were improperly sterilized as the VA has pointed out. This again is alarming to know that patients were susceptible to bio-matter due to these findings.

OSC Question 7: *Is the VA seeking disciplinary action for employees stemming from the findings of the OMI investigation? If so, what action is being sought and for what reason?*

VA Response 7: The recommendation for an administrative investigation board (AIB) was associated with the Censitrac system. A fact finding completed March 2, 2016, did not recommend an AIB, as all the individuals who made decisions about Censitrac implementation were no longer employed at the Medical Center.

A. Smith III Response 7: I had the opportunity to speak with my former SPS Supervisor, John Christian in September 2016. Mr. Christian communicated that the implementation decisions regarding the Censitrac tracking software system was an SPS joint management consensus, meaning all of the past and present SPS management team was responsible for implementation of the Censitrac software tracking system. Mr. Christian further alleged:

- Susan Heyward departed the facility in April 2016;
- Stephanie Bobelieu-Boone is still employed at the at the RGM VAMC as assistant chief;
- Robert Coffey is still employed as 1st shift supervisor.

Mr. Christian also stated that Mrs. Susan Heyward, Mrs. Stephanie Bobelieu Boone and Mr. Robert Coffey were detailed to another department within the RGM VAMC by the Office of the Director. I confirmed that Mrs.

Heyward did depart the RGM VAMC in April 2016; Mrs. Stephanie Bobelieu-Boone and Mr. Robert Coffey are both still employed in management roles in the SPS department at the RGM VAMC. WHY? This appears to be another instance of the Office of the Director (VA) deliberately covering the backside of SPS management. How could the OMI not know these personnel were still were still employed at the RGM VAMC?

Conclusion: *Unfortunately it seems the same sort of attitude that created the VA scandals is still alive and well within the department. That's because…in a bizarre attempt to defend the departments lack of accountability…VA leaders have adopted the puzzling strategy of downplaying and making excuses for instances of employee misconduct that every objective observer knows is abhorrent.* (Miller, B. R. 21 Aug. 2016).

In reviewing the Office of the Medical Inspectors report and supplemental answers to the Office of Special Counsel, I am left with the belief that this investigation found the Sterile Processing Service solely responsible for the majority of the allegations they were investigating. If this is so, how could a healthcare facility knowingly operate in this fashion with its administration being unaware? The OMI points out that there were either no records or there were no reports…Please consider the serious implications of these *few* issues that was brought out by the OMI report:

1. There were eight (8) biological failures from the SPS steam sterilizers over a seven (7) month period; this translates to at least one a month which is an indication of a systemic problem with the maintenance of the sterilizers. The quality of *all* sterilized loads should be in questioned. **According to the guidelines, eight (8) failures in seven months is an extremely high rate of failures**; why wasn't this substantiated?
2. There was no documented quality monitoring of the critical and semi-critical RME from the OR to the SPS decontamination unit; how could the OMI *not* substantiate the allegation when they could not validate that reprocessing time occurred within guideline protocols?
3. Prepzyme does not kill microbial bacteria that is allowed to attach itself within the channels and lumens of RME; the enzymatic that was utilized to clean the RME was not utilized in accordance with manufacturer's instructions, so how can the OMI not substantiate my allegation?
4. SPS technicians were permitted to reprocess RME with information (SOPs) that was outdated for years. How could the OMI not substantiate my allegation? Rewrite the SOPs and all is well?

In a conversation with Thomas Kramer, an Olympus Technical Support Engineer, I asked "how long should an endoscope that is not reprocessed in a timely manner be presoaked for with enzymatic solution?" He informed me that according to the manual, the basic guidance is no more than ten (10) hours. I can attest to the fact that endoscopes were pre-soaked for no more than one (1) hour in the SPS decontamination unit

The inability of the SPS technicians to competently provide basic knowledge to the OMI is due to the fault of the technicians. It is also serves as validation of the lack appropriate training and leadership by SPS management past and present. It is aggravating to know that the RGM VAMC Office of the Director mislead the OMI in regards to the employment status of the SPS management personnel in regards to disciplinary actions in regards to Censitrac software tracking system that is truly warranted. $150,000.00 of taxpayer monies should not be overlooked. My summation of the VA statement, "*…A fact finding completed March 2, 2016, did not recommend an AIB, as all the individuals who made decisions about Censitrac implementation were no longer employed at the Medical Center."*

The OMI was provided information by the Office of the Director that was incorrect. At the time of the fact finding, Mrs. Susan Heyward, Mr. Robert Coffey and Mrs. Stephanie Bobelieu-Boone were still employed at the RGM VAMC and available for the recommended Administrative Investigation Board. Preserving and safeguarding management's reputation should not take precedence over the untold number of healthcare workers and veterans that the Raymond G. Murphy Veterans Affairs Medical Center placed at risk.

Lastly, but not in the least unimportant, with the rapid outbreak of infectious diseases such as CRE, we must ensure that we as sterile processing professionals remain ever competent and vigilant. The results of the VHA endoscopy hearings of 2009 and the 2014 VHA scandal demonstrates that the VA and the VHA corrosive culture is alive and well, despite their leader's promises to the American people. This system continues to renege on their empty promises to keep our healthcare workers and veterans safe. It is time we do more than simply have more hearings.

Attachments

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Suggested Readings

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